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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,618	12/22/2004	Michael F. Holick	2317.0430001/RWE	8983

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EXAMINER

WINTERBERG, NISSA M

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

09/03/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/518,618

Applicant(s)

HOLICK ET AL.

Examiner

Nissa M. Westerberg

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 - 14 is/are pending in the application.
- 4a) Of the above claim(s) 3 - 7 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 8 - 11 is/are rejected.
- 7) ☒ Claim(s) 12 - 14 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Applicants' arguments, filed June 12, 2008, have been fully considered. The following rejections and/or objections constitute the complete set presently being applied to the instant application.

Amendments

The claims of the instant application have been amended to recite a NSAID covalently linked to a sugar. Support for the covalent linkage can be found in formula I in ¶ 12 of the instant specification and the exemplified compounds in the two moieties are covalently linked to one another.

Claim Objections

1. Claims 12 – 14 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1, 2 and 8 – 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. (US 5,695,738).

Anderson et al. discloses compositions of steroidal glycosides wherein the steroidal compound is linked directly or indirectly to the glycoside (abstract). Methods of using the compositions to treat patients with inflammation and autoimmune diseases (abstract). Among the carbohydrates whose glycosides can be used in the present invention include glucose and amino sugars (col 7, ln 42 – 57). The compounds are preferentially administered with a pharmaceutical carrier (col 12, ln 9 – 14). A “linker” is defined as that which joins or connects separate parts of a molecule and can be a moiety, molecule or group of molecules attached to a substrate (col 8, ln 31 – 43). The linker groups attached to the steroidal C-glycoside compounds can be used to attach additional compounds such as pharmaceutically acceptable drugs (col 14, ln 43 – 47). NSAIDs such as naproxen or ibuprofen could be administered bound to the steroidal C-glycoside (col 14, ln 54 – 57).

Anderson et al. does not explicitly prepare NSAID/steroidal C-glycoside compounds.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to prepare an NSAID/steroidal C-glycoside compound as taught by Anderson et al. because such compounds could be administered systemically in smaller amounts than usual while obtaining an equivalent effect of even greater anti-inflammatory effect at the site of inflammation (col 14, ln 57 – 60).

6. Claims 1 and 8 – 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wiessler et al. (WO 97/02046; all citations from the English equivalent US 6,489,302).

Wiessler et al. discloses a conjugate comprising a saccharide and one or more therapeutic or diagnostic agents (col 1, ln 17 – 19). The conjugates provide a product by which agents of the most varying kinds can be transported in a good fashion to the site of action (col 1, ln 11 – 14). Among the possible saccharides which may be used in the conjugate are glucose and 2-amino-2-deoxyglucose (col 1, ln 30 - 43). Every therapeutic and/or diagnostically usable substance can be considered (col 1, ln 44 – 45), but the NSAID analgesics indomethacin, paracetamol, ibuprofen and acetylsalicylic acid are mentioned explicitly (col 1, ln 62 – 63). The conjugates of the invention are suited for treating diseases such as Alzheimer's disease, Parkinson's disease (col 2, ln 25 – 26) and some conjugates can be used to treat inflammations such as rheumatic arthritis (col 2, ln 39 – 42). One of the compounds was synthesized and administered by i.v. injection to rats (col 4, ln 21 – 23), a use which requires the use of a pharmaceutically acceptable carrier.

Wiessler et al. does not explicitly prepare an analgesic-saccharide conjugate or use it to treat a condition associated with inflammation.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to prepare an analgesic-saccharide conjugate to improve the transport of the analgesic active ingredient as taught by Wiessler et al.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8:00 a.m. - 4 p.m. ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

NMW